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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,563	08/31/2000	Martin Winn	5594.US.P9	4178

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ROBERT DEBERARDINE  
ABBOTT LABORATORIES  
100 ABBOTT PARK ROAD  
DEPT. 377/AP6A  
ABBOTT PARK, IL 60064-6008

EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/653,563

Applicant(s)

WINN ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on responses filed on 09/06, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,21 and 66-191 is/are pending in the application.
- 4a) Of the above claim(s) 1,21,66-169,172-174,177-184 and 187-189 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 170,171,175,176,185,186,190 and 191 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's remarks/arguments filed on September 06, 2005, is acknowledged. Claims 1, 21, and 66-191 are pending in the application.

#### ***Responses to Arguments***

2. Applicant's arguments regarding rejection of claims 171, 176, 186, and 191 under 35 U.S.C. 112, first paragraph, filed on September 06, 2005, have been fully considered and they are persuasive. The instant claimed method of use, i.e., treating pain associated with bone cancer, has been found on the page 792, lines 3-4. Therefore, rejection of claims 171, 176, 186, and 191 under 35 U.S.C. 112, first paragraph, has been withdrawn.

#### ***New Grounds of Rejection***

3. Applicant's arguments with respect to claims 170-171, 175-176, 185-186, and 190-191 have been considered but are moot in view of the new grounds of rejection.

#### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 170-171, 175-176, 185-186, and 190-191 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 10 of Winn et al. US 5,767,144. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a method of use treating nociception or bone pain using a compound, trans,trans-2-(4-methoxyphenyl)-4-(1,3-benzodioxol-5-yl)-1-(N,N-di(n-butyl)aminocarbonylmethyl)-pyrrolidine-3-carboxylic acid. The instant methods of use of compounds of formula (I) or the compound trans,trans-2-(4-methoxyphenyl)-4-(1,3-benzodioxol-5-yl)-1-(N,N-di(n-butyl)aminocarbonylmethyl)-pyrrolidine-3-carboxylic acid, have been found on the pages 1-15 and 787-793 of the specification.

Winn et al. claim a method of use (i.e., antagonizing endothelin or treating nociception or bone pain) using a compound, trans,trans-2-(4-methoxyphenyl)-4-(1,3-benzodioxol-5-yl)-1-(N,N-di(n-butyl)aminocarbonylmethyl)-pyrrolidine-3-carboxylic acid, see column 190, lines 40-63, column 191, lines 17-19, and column 193, lines 41-43.

The difference between the instant claims and Winn et al. is that Winn et al. silence the instant claimed particular methods of use (i.e., treating nociception or bone pain).

One having ordinary skill in the art would find the claims 170-171, 175-176, 185-186, and 190-191 prima facie obvious because one would be motivated to employ the methods of use of Winn et al. to obtain instant methods of use, wherein the compound, trans,trans-2-(4-methoxyphenyl)-4-(1,3-benzodioxol-5-yl)-1-(N,N-di(n-butyl)aminocarbonylmethyl)-pyrrolidine-3-carboxylic acid, is used for treating nociception or bone pain (i.e., antagonizing endothelin).

The motivation to make the claimed methods of use derives from the expectation that the instant claimed methods of use from the known Winn et al. methods of use using the same compound, would possess similar activity (i.e., antagonizing endothelin or treating nociception or bone pain) to that which is claimed in the reference.

### ***Objection***

6. Claims 1, 21, 66-169, 172-174, 177-184, and 187-189 are objected to as being non-elected inventions. Elimination of claims 1, 21, 66-169, 172-174, 177-184, and 187-189 would obviate the objection.

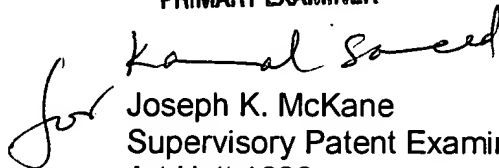
***Telephone Inquiry***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KAMALA A. SAEED, PH.D.  
PRIMARY EXAMINER

  
for Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626

  
Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

October 14, 2005